

**Louisiana Medicaid**  
**Heart Disease – Hyperlipidemia – Lipotropics (Other)**

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request:

- Prior authorization for non-preferred lipotropic (other) agents
- Clinical authorization for alirocumab (Praluent®), evolocumab (Repatha®), evinacumab-dgnb (Evkeeza™) and lomitapide (Juxtapid®)

Additional Point-of-Sale edits may apply.

*These agents may have a **Black Box Warning(s)** and may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

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**Approval Criteria for Non-Preferred Lipotropics (Other) Agents (Other than Evkeeza™, Juxtapid®, Praluent®, and Repatha®)**

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product – **ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
  - The prescriber states that the recipient is currently using the requested medication **AND ONE** of the following applies:
    - There is evidence in pharmacy claims of at least 60 days of the requested medication within the previous 90-day period; **OR**
    - There is evidence in pharmacy claims of less than 60 days of the requested medication **AND** the prescriber states the recipient has been treated with the requested medication in an inpatient facility; **OR**
    - There is evidence in pharmacy claims of less than 60 days of the requested medication **AND** the prescriber has verified that the pharmacy has dispensed at least 60 days of medication (billed to other insurance, and therefore not viewable in pharmacy claims); **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

## Duration of authorization approval: 12 months

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### Alirocumab (Praluent®)

### Evolocumab Subcutaneous SureClick; Pushtronex; Syringe (Repatha®)

#### Approval Criteria

- The recipient has **ONE** of the following diagnoses [age requirements apply]:
  - atherosclerotic cardiovascular disease [18 years of age or older]; **OR**
  - primary hyperlipidemia (heterozygous familial hypercholesterolemia [HeFH]) [18 years of age or older]; **OR**
  - homozygous familial hypercholesterolemia (HoFH) [For Praluent® – 18 years of age or older; For Repatha® – 13 years of age or older]; **AND**
- The requested medication is prescribed by, or the request states that this medication is being prescribed in consultation with, either a cardiologist or specialist in the treatment of lipid disorders; **AND**
- The recipient has received the maximum FDA-approved dose of a statin agent for at least 12 consecutive weeks without adequate response, **OR** has a documented intolerance to, or contraindication to statin agents [the name of the statin agent and date range of treatment are **stated on the request**]; **AND**
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product – **ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - Other treatment options (e.g., niacin or bile acid sequestrants) will be prescribed concomitantly if the recipient is intolerant to statins; **AND**
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

## Duration of initial approval: 6 months

#### Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

## Duration of reauthorization approval: 12 months

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### Evinacumab-dgnb (Evkeeza™)

#### Approval Criteria

- The recipient is 12 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of homozygous familial hypercholesterolemia (HoFH); **AND**
- The recipient is currently receiving at least **ONE** low-density lipoprotein-cholesterol (LDL-C) lowering agent, the name of which is **stated on the request**; **AND**
- Evkeeza™ is prescribed by, or the request states that this medication is being prescribed in consultation with, either a cardiologist or specialist in the treatment of lipid disorders; **AND**
- The recipient has a documented failure of, or intolerance to, or contraindication to an adequate trial (3 months) of a statin agent [the name of the statin agent and date range of treatment are **stated on the request**]; **AND**
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product – **ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The recipient does not have other causes of hypercholesterolemia, including those with heterozygous familial hypercholesterolemia (HeFH); **AND**
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

## Duration of initial approval: 6 months

#### Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The recipient is currently receiving at least **ONE** low-density lipoprotein-cholesterol (LDL-C) lowering agent, the name of which is **stated on the request**; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

## Duration of reauthorization approval: 12 months

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## Lomitapide (Juxtapid®)

### Approval Criteria

- The recipient is 18 years of age or older; **AND**
- The recipient has a diagnosis of homozygous familial hypercholesterolemia (HoFH); **AND**
- Juxtapid® is prescribed by, or the request states that this medication is being prescribed in consultation with, either a cardiologist or specialist in the treatment of lipid disorders; **AND**
- The recipient has a documented failure of, or intolerance to, or contraindication to an adequate trial (3 months) of a statin agent [the name of the statin agent and date range of treatment are **stated on the request**]; **AND**
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product – **ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

**Duration of initial approval: 6 months**

### Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

**Duration of reauthorization approval: 12 months**

## References

Evkeeza (evinacumab-dgnb) [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc; February 2021.  
[https://www.regeneron.com/sites/default/files/Evkeeza\\_PI.pdf](https://www.regeneron.com/sites/default/files/Evkeeza_PI.pdf)

Goldberg, A, et al. Familial hypercholesterolemia: screening, diagnosis and management of pediatric and adult recipients: clinical guidance from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. Journal of Clinical Lipidology 2011;5(3S): 1-15.  
[www.lipid.org/sites/default/files/articles/familial\\_hypercholesterolemia\\_1.pdf](http://www.lipid.org/sites/default/files/articles/familial_hypercholesterolemia_1.pdf)

Jellinger P, et al. 2017 American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for the Management of Dyslipidemia and Prevention of Cardiovascular Disease. Endocrine Practice 2017;23(Suppl. 2):1-87.  
<https://www.aace.com/files/lipidguidelines.pdf>

Juxtapid (lomitapide) [package insert]. Cambridge, MA: Aegerion Pharmaceuticals Inc; September 2020.  
<http://www.juxtapid.com/prescribing-information>

Praluent (alirocumab) [package insert]. Bridgewater, NJ: Sanofi-Aventis US LLC; April 2021.  
[https://www.regeneron.com/sites/default/files/Praluent\\_PI.pdf](https://www.regeneron.com/sites/default/files/Praluent_PI.pdf)

Repatha (evolocumab) [package insert]. Thousand Oaks, CA: Amgen Inc; February 2021.  
[https://www.pi.amgen.com/~media/amgen/repositorysites/pi-amgen-com/repatha/repatha\\_pi\\_hcp\\_english.pdf](https://www.pi.amgen.com/~media/amgen/repositorysites/pi-amgen-com/repatha/repatha_pi_hcp_english.pdf)

Stone N, et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults. Circulation 2014;129(Suppl. 2):S1–S45 DOI: 10.1161/01.cir.0000437738.63853.7a

Revision / Date	Implementation Date
Single PDL Implementation	May 2019
Updated diagnosis for Praluent®, added Evkeeza™, updated references, removed defining parameters for diagnosis, formatting changes / May 2021	October 2021
Formatting changes, removed quantity limits for Praluent®, Repatha®, and Juxtapid® / August 2021	January 2022